

Toby Port
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CLAIMS

What is claimed is:

1. A liquid pharmaceutical composition of a GABA analog comprising at least one polyhydric alcohol containing 2 to 6 carbon atoms and wherein said composition has a pH of about 5.5 to about 7.0.
2. The composition according to Claim 1, wherein the polyhydric alcohol contains 3 to 5 carbon atoms and wherein the content of polyhydric alcohol is about 25% to about 75% weight/volume (w/v).
3. The composition according to Claim 2, wherein the polyhydric alcohol is selected from the group consisting of: glycerol, xylitol, sorbitol, mannitol, and a mixture of glycerol and xylitol, and wherein the content of polyhydric alcohol is about 40% to about 75% weight/volume (w/v).
4. The composition according to Claim 1, wherein the pH is about 6.0 to about 7.0.
- 15 5. The composition according to Claim 1, comprising one or both of: (a) an additional preservative; and (b) an additional flavor improver which does not contain an aldehyde or keto functionality.
6. A method for preparing a liquid pharmaceutical composition of a GABA analog comprising:
 - Step (1) adding a polyhydric alcohol containing 2 to 6 carbon atoms to water;
 - Step (2) adding a GABA analog to the solution from Step (1); and
 - Step (3) optionally, adjusting the pH of the composition to about 5.5 to about 7.0 to afford the liquid pharmaceutical composition.

7. The method according to Claim 6, wherein the polyhydric alcohol is a mixture of glycerol and xylitol.
8. The method according to Claim 6, wherein the content of polyhydric alcohol is about 25% to 75% (w/v) and the pH is about 6 to about 7.
- 5 9. A two-component liquid pharmaceutical composition of a GABA analog comprising (a) a first component comprising a powder mixture of a GABA analog and a solid polyhydric alcohol; (b) a second component comprising a liquid base wherein the powder component from (a) is added to the liquid base from (b) to afford a liquid pharmaceutical composition.
- 10 10. A method for preparing a two-component liquid pharmaceutical composition of a GABA analog comprising:
Step (1) mixing a GABA analog with a solid polyhydric alcohol to afford a powder mixture;
Step (2) mixing a polyhydric alcohol with a sweetener and a flavor in water to afford a liquid base; and
Step (3) adding the powder mixture to the liquid base to afford the liquid pharmaceutical composition.
- 15 11. The method according to Claim 10, wherein the GABA analog is gabapentin or pregabalin.
- 20 12. The composition according to Claim 1 or Claim 9 wherein the GABA analog is gabapentin or pregabalin.
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13. The composition according to Claim 1 or Claim 9 wherein said composition has less than 0.5% by weight of the corresponding lactam of the GABA analog.
- 25 14. An aqueous oral pharmaceutical composition of gabapentin or pregabalin, characterized by a content of at least 25% (w/v) of at least one polyhydric

aliphatic alcohol containing 2 to 6 carbon atoms and a pH of about 5.5 to about 7.0 containing, less than 0.5% (w/w) of gabapentin lactam or pregabalin lactam, respectively, after storage at 2°C to 10°C for 18 months to 2 years.

- 5 15. The pharmaceutical composition according to Claim 1 or Claim 13 for the treatment of a subject suffering from cerebral diseases, including epilepsy, faintness attacks, hypokinesia and cranial traumas, neurodegenerative disorders, depression, mania and bipolar disorders, anxiety, panic, inflammation, renal colic, insomnia, gastrointestinal damage, incontinence, 10 pain, including neuropathic pain, muscular pain, skeletal pain, and migraine.